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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,197	10/26/2001	Martin J. Wensley	509032001500	1701

7590 12/15/2003

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

11

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/057,197

Applicant(s)

WENSLEY ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-134 is/are pending in the application.
- 4a) Of the above claim(s) 66-123 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38, 44-47, 54-57, 65 and 124-134 is/are rejected.
- 7) ☒ Claim(s) 39-43, 48-53 and 58-64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 66-123 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 4, 12, 14, 15, 18-20, 23-30, 34, 36, 44, 45, 54-57, 65, 124 and 131 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,095,153 to Kessler et al.
5. Kessler teaches a method for generating an aerosol comprising the steps of heating a physiologically active compound to vaporize the compound (col. 5, lines 47-

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63); and mixing the resulting vapor with a gas (air) in a ratio (via air inlet **29**; col. 6, lines 64-67) to form a desired particle size when a stable concentration of particles in the gas is reached; wherein the ratio of vapor to gas is controlled by regulating the rate of vaporization (by removing the delivery means **14** to limit further vaporization; col. 5, line 63-66); wherein the compound is moved in a heating zoned during heating; wherein the compound is deposited into a substrate; wherein the compound is vaporized below the boiling point since a gas is passed across the surface of the compound; wherein the gas is air; wherein the compound is nicotine (col. 1, line 32); wherein the compound is heated for a period of time (since the delivery means is removable); wherein the gas is mixed closely to mix the compound; wherein the mixing is done to prevent increase in gas temperature; wherein the gas temperature is maintained at 10 deg. C; wherein the gas low rate is constant and laminar (col. 8, lines 32-33); wherein a thin film of the compound is deposited; wherein the compound is heated in a container **12**; wherein the substrate has a low thermal conductivity; wherein the compound is deposited onto a thermally conductive substrate that is heated; wherein the compound is contained in a heating-vaporization zone; wherein the vapor is administered to a patient; wherein the compound is heated sequentially (one delivery after another)

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16, 17, 21, 22, 46, 47, 128-130 and 132-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al.

8. As to claims 16, 17, 46 and 47, Kessler is silent with regards to the particle size in the range of 10 nm to 3 micron. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the particle size in the recited range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

9. As to claims 21 and 22, Kessler is silent with regards to the period of time in the recited range of the claims. However, Kessler teaches that the heating device can be turned off at anytime and the delivery device can be removed from the heating device to control vaporization. Therefore, it would have been a mere matter of design choice available to one of ordinary skill in the art to have the time period be in a selected range which could be attained through observation and experimentation.

10. As to claim 128, Kessler is silent with regards to the high current step being supplied by discharging a capacitor. However, it would have been obvious to one of ordinary skill in the art to use the recited heating step because it is well known in the art to use capacitors or high current elements as heaters.

11. As to claims 129 and 130, Kessler is silent with regards to the time being between 2-20 ms. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the time in the recited range because it has

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been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. As to claims 132-134, it is well known in the art to use vaporizers to provide mist to a user's eye, skin or mucousa and would have been obvious to one of ordinary skill in the art.

13. Claims 2, 3, 5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of US 5,918,595 to Olsson et al.

14. As to claims 2, 5 and 10, Kessler is silent with regards to regulating the ratio of the vapor to gas by controlling the flow rate of the gas. Olsson teaches a vaporizer in which the gas flow rate is regulated to control the delivery of the vapor along with the gas (col. 4, lines 6-20). Therefore, it would have been obvious to modify the method of Kessler to include the regulating step taught by Olsson because it is well known in the art and available to one of ordinary skill to regulate the flow of gas to vary the ratio of vaporized medicament to gas.

15. As to claims 3 and 7, Kessler teaches the step of regulating the rate of vaporization (by removing the delivery means **14** to limit further vaporization; col. 5, line 63-66).

16. As to claims 8 and 9, Kessler teaches that the vaporization rate is controlled by manipulating the temperature.

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17. Claims 6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of US 5,918,595 to Olsson et al. and in further view of US 5,592,934 to Thwaites.

18. As to claims 6 and 11, Kessler/Olsson is silent with regards to an annunciating signal. Thwaites teaches an alarm to alert a patient (col. 5, lines 27-37). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the alarm of Thwaites to Kessler/Olsson because it alerts the user/patient if the device is malfunctioning or operating outside the normal parameters.

19. As to claim 13, Kessler teaches stopping the compound from being vaporized.

20. Claims 31-33, 35, 37, 38 and 125-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kessler et al. in view of US 5,366,770 to Wang.

21. As to claim 31, Kessler is silent with regards to the compound by heating the substrate through an alternating magnetic field. Wang teaches a vaporizer using magnetic fields/induction to heat a compound (col. 4, lines 53-59). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any well known heating step, including the heating step of Wang, since the Applicant has not disclosed that the specific type of heating step solves any stated problems or is for any particular purpose and it appears that the invention would perform equally well with the step taught by Wang.

22. As to claims 32, 33, 125-127, Wang teaches the use of a mesh, metallic, stainless steel foil (col. 6, lines 51-54).

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23. As to claim 35, Kessler/Wang is silent with regards to the thickness of the deposited compound. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the thickness in the recited range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

24. As to claims 37 and 38, Wang teaches the field maintained at 1 MHz but is silent with regards to 100-300 kHz. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the thickness in the recited range because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Allowable Subject Matter

25. Claims 39-43, 48-53 and 58-64 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe



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